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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,961	05/30/2006	Marie Eskling	4614-0182PUS1	9435
2292 7590 03/24/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER BASU, NIRMAL SINGH				
ART UNIT 1646		PAPER NUMBER		
NOTIFICATION DATE 03/24/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/560,961

**Applicant(s)**

ESKLING ET AL.

**Examiner**

NIRMAL S. BASI

**Art Unit**

1646

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-35, 45 and 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-44 and 46 is/are rejected.
- 7) ☒ Claim(s) 38, 40, 42, 44 and 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/16/06, 5/31/06, 12/14/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election with traverse of Group III (Claims 36-44 and 46) on 8/26/08 is acknowledged. The traversal is on the ground(s) that the examiner has misinterpreted and wrongly applied PCT Rule 13.2 and examiner has improperly focused on only the method for purification of EGFR family derived proteins. Applicants arguments have been fully considered but they are not found persuasive. Claim 1 is directed to a method for purification of an EGFR family derived receptor protein and the Examiner has properly focused on said claim to determine inventive concept.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) Document D1 (documents submitted with 371 Application on 12/14/05), which is considered to represent the most relevant state art, discloses (abstract; sections 2.3.4-2.3.6; page 116, left column, lines 1-3) a method for the purification of a recombinant protein comprising dialysis, metal affinity chromatography, size exclusion chromatography, anion exchange chromatography. From this, the subject-matter of claim 1 differs in that a method for the purification of another protein is claimed. The problem to be solved by present claim 1 may therefore be regarded as the provision of a method for the purification of a protein. The solution proposed, namely the provision of a method for the purification of an EGFR family derived protein (such as HER-2) cannot be considered as involving an inventive step for the following reasons: In view of the disclosure in document D1, the skilled person would regard it as obvious to combine several purification methods, such as those disclosed in D1 for the purification of HER-2. The skilled person would proceed without the use of inventive skill, using common knowledge and routine only, with a reasonable expectation of success. In conclusion, the subject-matter of claim 1 does not involve an inventive step. The subject matter of claims 2-33 does not seem to add subject matter that would render this part of the application inventive. Therefore, the subject matter of claims 1-33 does not satisfy the criterion set forth in Article 33(3) PCT.

b) The identification of a suitable purification scheme is an elaborate process which requires a lot of experimentation before a useful set of steps are found for the particular protein and raw material in question. Finding an advantageous combination of methods amongst a large number of possibilities is certainly time consuming. However, the method as claimed is a normal combination of standard techniques that the person skilled in the art would consider. There not appear to be a surprising effect linked to the specific combination. In conclusion, no inventive step can be acknowledged at present.

The method of purification used in the claimed methods lacks an inventive step and therefore a technical relationship does not exist between the claimed groups. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

Claims 1-35, 45, 47-53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The requirement is still deemed proper and is therefore made FINAL.

### **Objections**

2. The disclosure is objected to because of the following informalities:

Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 3, Applicant has written "LEGENDS TO THE FIGURES"

Appropriate correction is required.

3. Objections to the claims

Claims 38 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 38 is dependent on a multiple dependent claim 36. See MPEP § 608.01(n). Accordingly, the claim 38 is not been further treated on the merits.

Claims 40 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 40 is dependent on claim 37 which is dependent on a multiple dependent claim 36. See MPEP § 608.01(n). Accordingly, the claim 40 is not been further treated on the merits.

Claims 42 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 42 is dependent on 42 which is dependent on a multiple dependent claims 36 and 42. See MPEP § 608.01(n). Accordingly, the claim 42 is not been further treated on the merits.

Claims 44 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 44 is dependent on 41 which is dependent on a multiple dependent claim 36. Further multiple dependent claim 42 is directly dependent on multiple dependent claim 36. See MPEP § 608.01(n). Accordingly, the claim 44 is not been further treated on the merits

Claims 46 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 46 is dependent on claim 42 which is dependent on a multiple dependent claim 36. Further multiple dependent claim 46 is dependent on claim 41 which is dependent on claim 37 which is dependent on a multiple dependent claim 36. See MPEP § 608.01(n). Accordingly, the claim 46 is not been further treated on the merits.

4. The drawings, filed 12/14/05, are approved by the examiner.

***Specification***

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36-44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. An amendment incorporating the limitations of base claim 34 or 35 into claim 36 would overcome the rejection.

Claim 36 recites the limitation ""HER-2 protein according to claim 34 or 35. There is insufficient antecedent basis for this limitation in the claim, claims 34 and 35 are non-elected. An amendment incorporating the limitations of base claim 34 or 35 into claim 36 would overcome the rejection.

Claim 40 is indefinite because it is not clear what is a "mini-chromosome" so as to allow the metes and bounds of the claim to be determined.

Claim 39 recites the limitation "the vector according to claim 37" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 40 recites the limitation "the vector according to claim 37 or 39" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 41 recites the limitation "the vector according to claim 37" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 43 recites the limitation "the vector according to claim 37" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 42 is indefinite because it is not clear what is "a nucleic acid sequence encoding a terminator". What is a "terminator".

Claim 44 recites the limitation ""HER-2 protein according to claim 34 or 35. There is insufficient antecedent basis for this limitation in the claim; claims 34 and 35 are non-elected. An amendment incorporating the limitations of base claim 34 or 35 into claim 44 would overcome the rejection.

Claims 37, 38, 42, 43 and 46 are rejected for depending on an indefinite base claim and failing to resolve the issues raised above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/  
Examiner, Art Unit 1646

/Michael Pak/  
Primary Examiner, Art Unit 1646